XRI®

An XR Imaging Network Company

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March 16, 1998

Dockets Management Branch
HFA-305
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Dear Sirs:

The following is in response to the four "issues relating to remarketing activities that do not significantly change the devices' performance or safety specifications or related uses."

1. The FDA has appropriately defined the terms refurbisher, " as-is" remarketer and servicers.

2. By its own admissions, the FDA (after meetings with the IAMER) realizes that many remarketing firms are unaware of the current FDA's regulations, i.e.- parts 820, 1002, and 1020 to name the more significant. Unless remarketing firms comply with the regulations currently issued by the FDA- for medical devices- the level of actual problems in the industry is mitigated. The added layer generated by the CGMP will not resolve this issue.

3. The "appropriate" levels of regulatory controls have already been issued by the FDA as described in the Federal Register Online via GPO Access:

Agency: Food and Drug Administration , HHS

Action: Advance Notice of Proposed Rulemaking

Supplementary Information, Section I- Background

4. In the background section noted in Item 3 above, refurbishers, " as-is" remarketers and servicers are included with rebuilt, reconditioned and cosmetically enhanced as being part of the definition of remarketing and its inherent regulations already issued by the FDA for medical devices; notwithstanding the fact that refurbishers, " as-is" remarketers and servicers do not perform activities that significantly change the devices' performance, et al.

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Subjectively, the intent of the FDA to obligate a class of remarketers to additional controls (who by FDA's definition-fall outside the control of the O.E.M.) for the public health is noble.

Objectively- the additional burden of more regulations (CGMP) is redundant. Enforce what has been currently issued. Allow refurbishers, " as-is" remarketers and servicers with the help of the IAMER and related associations to police its members. Those same members (with due education from the FDA) will be compelled to comply with the currently existing regulations issued by the FDA for medical devices (i.e. parts 820, 1002, and 1020 et al).

Respectfully,

Michael E. Butcher
Director of Operations, XRI
An XR Imaging Network Company

MEB/lm

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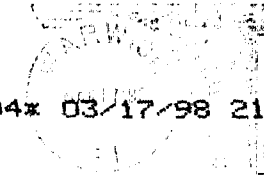

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